IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Demers, et al.	Art Unit:	1723
Appl. No:	10/696,818	Examiner:	Sorkin, D.
File Date:	October 30, 2003	Docket No.:	1062/D72
Invention:	Two-Stage Mixing System, Apparatus and Method		

CERTIFICATE OF MAILING

I hereby certify that this document, along with any other papers referred to as being attached or enclosed, is being deposited with the United States Postal Service as first class mail with sufficient postage in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on June 28, 2006.

Jeffrey T. Klayman

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Dear Sir:

Following a Final Office Action dated February 28, 2006, Applicants submit the present Request for Formal Review, by a panel of examiners, of the legal and factual basis of the rejections pending in the present case, in accordance with the Pre-Appeal Brief Conference Pilot Program[1]. Applicants believe that the issues presented are well-posed for appeal, and request formal review prior to appeal on the following grounds:

I. Background Synopsis of Subject Matter

The present application relates to combining a first substance with a second substance that cannot be mixed directly with the first substance without damaging at least one of the first substance and the second substance.

II. Synopsis of Status of the Case

Claims 9-12 and 35-58 are pending in the application. In the Final Office Action of February 28, 2006, Claims 9-12 and 35-58 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

[1] Official Gazette of the United States Patent and Trademark Office, vol. 1296, Number 2, (July 12, 2005).

A telephonic interview was held on March 27, 2006 between Examiner David Sorkin and Applicants' Attorney Jeffrey Klayman to discuss the final Office action of February 28, 2006. The parties discussed the Examiner's position that Applicant did not clearly describe the type of solution and how to determine the useful lifetime of the solution, and therefore did not enable "predetermined useful lifetime."

Applicants' Attorney explained that the claims are enabled because the claims do not require "determining the useful lifetime" and that the specification clearly discloses that the working solution has a useful lifetime and discloses how the useful lifetime is employed in the process. Applicants' Attorney further explained that, based on the clearly stated understanding that the working solution has a limited useful lifetime, someone of ordinary skill would be able to make and use the claimed invention involving "determining whether mixing ... can be completed within a predetermined useful lifetime of the first solution and mixing ... only if mixing ... can be completed within the predetermined useful lifetime of the first solution." No agreement was reached.

A response was filed on April 27, 2006 in which the Applicant pointed out that the burden of proving lack of enablement is on the Examiner. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). MPEP 2164.04 makes it clear that the Examiner must identify the factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. This can be done by making specific findings of fact, supported by the evidence, and then drawing conclusions based on these findings of fact. For example, doubt may arise about enablement because information is missing about one or more essential parts or relationships between parts which one skilled in the art could not develop without undue experimentation. In such a case, the examiner should specifically identify what information is missing and why one skilled in the art could not supply the information without undue experimentation. References should be supplied if possible to support a *prima facie* case of lack of enablement, but are not always required. *In re Marzocchi*, 439

F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). However, specific technical reasons are always required. MPEP 2164.04.

Applicants explained that the claims are fully enabled because the application certainly provides sufficient disclosure to teach a person of ordinary skill in the art how to make and use the invention without undue experimentation. The application explicitly states that the working solution has a limited useable lifetime and that blood processing is coordinated to occur within the useable lifetime of the working solution (see page 11, lines 4-6). It is also clear that the process controller maintains various timers and keeps track of the age of working solution, and prevents blood processing operations if the working solution becomes too old (see page 18, lines 3-13). It is also clear that a determination is made as to whether there is a sufficient amount of time for performing the blood processing operation before the working solution expires and that blood processing is prevented if it cannot be completed in time (see page 26, lines 25-29 and page 28, lines 24-26). Thus, it would have been clear to a person of ordinary skill in the art, for example, to implement a timer to monitor the useful lifetime of the working solution and to allow the secondary mixing to begin only if the mixing can be completed within the remaining useful lifetime of the first solution. To the extent the subject patent application is missing information about how to determine the useful lifetime of the working solution, a person of ordinary skill in the art could certainly determine a useful lifetime without undue experimentation (in actuality, the useful lifetime is likely reported by the manufacturer). Furthermore, the Examiner has failed to supply specific technical reasons why one skilled in the art could not supply the missing information without undue experimentation, and therefore has not made a prima facie case of non-enablement.

Thus, Applicants reiterated that the claims are fully enabled. Furthermore, Applicants reiterated (from Applicants' earlier office action response), that none of the cited references teach or otherwise suggest the claimed invention. The claims are therefore both enabled and allowable.

Applicants noted that at least one claim has been twice rejected and that, therefore, the application is ripe for appeal.

Applicants received an Advisory Action dated May 9, 2006 in which the Examiner essentially maintained his former position that the claims are not enabled.

The appeal, noticed concurrently herewith, is with respect to rejected claims 9-12 and 35-58.

III. Issues for Review Prior to Appeal

1. The rejection of claims 9-12 and 35-58 is improper and must be withdrawn because the claims are enabled.

The claims are enabled because the specification describes the invention in such terms that one skilled in the art can make and use the claimed invention without undue experimentation. MPEP 2164 et seq. sets forth the enablement requirement. Specifically, the information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. The purpose of the enablement requirement is to ensure that the invention is communicated to the interested public in a meaningful way. Even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).

Claim 9 currently reads as follows: A method for combining a first substance with a second substance that cannot be mixed directly with the first substance without damaging at least one of the first substance and the second substance, the method comprising:

mixing the first substance with a first liquid to produce a first solution, the first solution having a first predetermined concentration of first substance capable of being mixed directly with the second substance without damaging one of the first substance and the second substance;

determining whether mixing of the first solution with the second substance to produce a second solution having a second predetermined concentration of first substance

relative to the second substance can be completed within a predetermined useful lifetime of the first solution; and

mixing the first solution with the second substance to produce the second solution only if mixing of the first solution with the second substance to produce the second solution can be completed within the predetermined useful lifetime of the first solution.

The claim does not require "determining a useful lifetime of the first solution," but instead requires "determining whether mixing of the first solution with the second substance ... can be completed within a predetermined useful lifetime of the first solution." Thus, the act of determining (or predetermining) a useful lifetime is not an explicit element of the claim. In any case, the application explicitly states that the working solution has a limited useable lifetime and that blood processing is coordinated to occur within the useable lifetime of the working solution (see page 11, lines 4-6). It is also clear that the process controller maintains various timers and keeps track of the age of working solution, and prevents blood processing operations if the working solution becomes too old (see page 18, lines 3-13). It is also clear that a determination is made as to whether there is a sufficient amount of time for performing the blood processing operation before the working solution expires and that blood processing is prevented if it cannot be completed in time (see page 26, lines 25-29 and page 28, lines 24-26). Thus, it would have been clear to a person of ordinary skill in the art, for example, to implement a timer to monitor the age of the working solution and to allow the secondary mixing to begin only if the mixing can be completed within the remaining useful lifetime of the first solution. Furthermore, to the extent the subject patent application is missing information about how to determine the useful lifetime of the working solution, a person of ordinary skill in the art could certainly determine a useful lifetime without undue experimentation (in actuality, the useful lifetime is likely reported by the manufacturer).

Thus, the claims are enabled because the specification describes the invention in such terms that one skilled in the art can make and use the claimed invention without undue experimentation.

2. The rejection of claims 9-12 and 35-58 is improper and must be withdrawn because the rejection fails to establish a prima facie case for non-enablement.

The examiner has failed to set forth a prima facie case of non-enablement because the examiner has not identified why one skilled in the art could not determine a useful lifetime of the solution without undue experimentation. In order to establish a prima facie case for non-enablement, the examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) MPEP 2164.04 makes it clear that the examiner must identify the factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. This can be done by making specific findings of fact, supported by the evidence, and then drawing conclusions based on these findings of fact. For example, doubt may arise about enablement because information is missing about one or more essential parts or relationships between parts which one skilled in the art could not develop without undue experimentation. In such a case, the examiner should specifically identify what information is missing and why one skilled in the art could not supply the information without undue experimentation. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). References should be supplied if possible to support a *prima facie* case of lack of enablement, but are not always required. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). However, specific technical reasons are always required. MPEP 2164.04

The examiner has argued that the claims are not enabled on grounds that the specification provides no information concerning how to predetermine useful lifetime of the solution. Even if the examiner is correct, such that some experimentation would be required in order for a skilled artisan to predetermine useful lifetime of the solution, the examiner has not supplied specific technical reasons why one skilled in the art could not predetermine useful lifetime without undue experimentation. In actuality, the useful lifetime of the solution could be specified by the manufacturer.

Thus, the examiner has failed to set forth a prima facie case of non-enablement because the examiner has not identified why one skilled in the art could not determine a useful lifetime of the solution without undue experimentation.

3. The claims are patentable over the prior art cited by the examiner

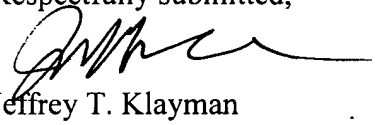
The Examiner had rejected the claims under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,136,586 (hereinafter "Budowsky").

Budowsky appears to disclose a two-step mixing process in which a solution of selective ethyleneimine oligomer inactivating agent is prepared in a first step and the solution of selective ethyleneimine oligomer inactivating agent is mixed with a phage-containing composition in a second step (see col. 17, lines 23-26). While Budowsky indicates that the solution of selective ethyleneimine oligomer inactivating agent is prepared immediately before use (see col. 16, lines 62-64), Budowsky does not appear to teach an explicit act of determining whether mixing of the first solution with the second substance to produce a second solution having a second predetermined concentration of first substance relative to the second substance can be completed within a predetermined useful lifetime of the first solution and mixing the first solution with the second substance to produce the second solution only if mixing of the first solution with the second substance to produce the second solution can be completed within the predetermined useful lifetime of the first solution, as required by claim 9.

Thus, the claims are allowable over Budowsky.

Allowance of claims 9-12 and 35-58 is respectfully requested.

Respectfully submitted,



Jeffrey T. Klayman
Registration No. 39,250
Attorney for Applicants

Bromberg & Sunstein LLP
125 Summer Street
Boston, MA 02110-1618
(617) 443-9292
01062/00D72 510861.1